IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:		10/621,972	Confirmation No.: 2230
Applicant	:	Ross S. Tsugita	Docket No.: 1001.1421103
Filed	:	July 17, 2003	Customer No.: 28075
TC/A.U.	:	3734	
Examiner	:	Blatt, Eric D.	
Title	:	FILTER FLUSH SYSTEM AND METHODS OF USE	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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By _____
JoAnn Lindman

Dear Sir:

Appellant has carefully reviewed the Final Office Action of October 14, 2009 and the Advisory Action of December 24, 2009. Currently, claims 53-80 remain pending of which claims 72-77 were previously withdrawn. Claims 53-71 and 78-81 have been rejected. Appellant notes that there is no currently pending claim 81. Appellant hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claim 63 was rejected under 35 U.S.C. 112, first paragraph, as failing to meet the written description requirement and Claim 78 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 78 to further prosecution of this case. As such, this latter rejection is considered moot.

Claims 53-58, 60-65, and 68-71 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (WO 99/22673), hereinafter Gray, in view of Patel (U.S. Patent No. 4,832,028). Although the Examiner did not point out how the claims were

being interpreted as suggested under MPEP 2173.06, Appellant attempted to respond in a manner consistent with the rejections found in the Office Action mailed October 14, 2009 to further prosecution.

Claims 59, 66, 67, and 78-80, there being no currently pending claim 81, were rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Patel as applied to claims 53 and 56, and further in view of Dubrul (U.S. Patent No. 6,258,115). [Initially, it should be noted that claims 79 and 80 do not depend from claims 53 and 56 and so it is unclear how Gray, Patel, and Dubrul is being applied to them.] After careful review, Applicant must respectfully traverse these rejections.

With respect to the 35 U.S.C. 112, first paragraph rejection of claim 63, it is noted that:

> If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient"). (MPEP 2163. II., 3., (a).)

It is believed that one of ordinary skill in the art would understand that an infusion lumen in the catheter of claim 53 from which claim 63 depends, said lumen being adapted for infusion of fluid or pharmaceutical agents, would be in fluid communication with the proximal end region of the catheter to allow the introduction of the fluid or pharmaceutical agents. As depicted, the infusion lumen (33) extends well proximal of the balloon. (See Fig. 1B.) As noted, there is no requirement that the description be in *ipsis verbis* to be adequate.

Further, the Examiner has asserted in the Final Office Action that Patel teaches a catheter which "has an end region extending from port 27 to the distal tip of the catheter. The portion of this end region that lies proximal of the balloon is considered a proximal end region". (Emphasis added.) Under the Examiner's interpretation, any portion of a catheter which lies proximal of the balloon would appear to provide "a proximal end region" said to be missing from the specification. Examination of Figs. 2C, 3C, and 4C will show fluid infused through infusion lumen (33) from a point proximal of the balloon indicating the presence of the infusion port of the claim and the specification, said port

being located proximal of the balloon and thus located in a proximal end region as the Examiner has considered that term. Even lacking this somewhat unusual interpretation of a proximal end, Figs. 2C, 3C, and 4C indicate that fluid enters the proximal most illustrated end of catheter (30) and so the illustrated proximal end of catheter (30) provides a port located at the proximal end region. Appellant respectfully requests that the rejection be withdrawn.

With regard to the §103 rejections over Gray in view of Patel, the Examiner has acknowledged that: "Gray fails to disclose a first shaft (claim 53) or outer catheter shaft (claim 68) with a balloon coupled thereto." Furthermore, nowhere does Gray appear to disclose, "wherein the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded". The Examiner has erred by arguing that the presence of a path which potentially bypasses the balloon associated with the first shaft and outer catheter shaft, said path found only in Fig. 5, is claimed by the Appellant in claims 63 and 64. Instead, those claims specify that the infusion port is within the proximal end region of the first catheter shaft as discussed above. The distal port (70) of the embodiment of Fig. 5 is not currently recited in claims 63 and 64. It is only the Examiner's assertion that distal port 27 of Patel may be considered to be located within "a proximal end region" which allows port 70 to be considered to be located anywhere but near the distal end of the catheter in question. Additionally, there is no requirement, or presumption, that every embodiment discussed in an application must necessarily be found in the claims presented, else it would not be proper to make an election in response to a restriction requirement or to cancel claims. Appellant notes that it is only blood outside of the catheter and proximal of the balloon which is said to be stopped when the balloon is inflated. As noted at, for example, page 12, lines 18-19: "Fluid or blood is infused through lumen 33 of the guiding catheter to flush the embolic material not cleared as a result of low-flow state toward filter 20." This flow of blood within the shaft or catheter is that found in claim 64 and is not excluded by claim 53.

Contrary to the Examiner's assertion, Appellant does not regard an inflow through port 70, and subsequently out the distal end of the shaft, to be compatible with the limitation that blood exterior to the catheter is stopped when the balloon is inflated.

Further, the mere presence of a port 70 adjacent to the distal balloon is insufficient to necessarily indicate that blood exterior to catheter and proximal of the balloon is able to enter port 70 thereby bypassing the balloon. So long as the pressure of fluid delivered within the lumen of the catheter is greater than the pressure of blood within the vessel and exterior to the catheter, all fluid flow through port 70 will be outward through the port thereby preventing inflow of blood which might reach the region distal of the catheter and satisfying the limitation of claim 53.

In the Response to Arguments which accompanied the Final Office Action, the Examiner appears to reverse the argument advanced above by arguing that the port 27 of Patel does allow blood to flow through the interior of the catheter as explicitly excluded by the claim. Further, Patel states: "Further, although the balloon 25 on the guiding catheter 11 contacts the inner surface of the coronary artery 19, blood flow is not restricted. Blood is perfused through the side hole 27 in the guiding catheter 11." Here the Examiner's position appears to be that the claims limit the path taken by blood located outside the catheter and proximal of the inflated balloon is limited in a way not recited in the claim, namely that flow through the port 27 of Patel, through the lumen and thus through the interior aperture defined by the toroidal balloon is permitted and that only flow between the balloon and the vessel wall is to be stopped by the balloon. The limitations of independent claims 53 and 68 only state:

"the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft".

Nothing in that language specifies a path. The disclosure of Patel (col. 2, lines19-23) explicitly allows that internal path and thus fails to provide the claimed limitation:

"The side hole 27 passes through the guiding catheter 11 to allow blood to flow from the aorta 13, through the side hole 27, and out the tip 21 of the guiding catheter 11."

Thus Gray in view of Patel fails to teach all the claim limitations of independent claims 53 and 68, as is required to establish a *prima facie* case of obviousness.

In the third section of the Advisory Action, the Examiner turns to the issue of whether the combination of Gray and Patel may reasonably be said to render obvious "a

self-expanding stent coupled to the inner catheter shaft". Patel does not appear to teach a stent. Gray does appear to disclose a stent; however that stent is not self-expanding and is not retained in a collapsed condition by a retaining sleeve as acknowledged by the Examiner in the Final Office Action. The inner catheter of Gray appears only to provide the guidewire and filter, but does not appear at any time to have a stent, self-expanding or other wise, associated therewith. Rather than addressing these deficiencies, the Advisory Action states: "Examiner sees no reason why this modification would not have been possible or would prevent the intended function of the Gray device. This assertion does not provide a motivation to combine the references and such a modification would impermissibly alter the operating principle of Gray which employs a thin catheter (20) which advances over a trackable path determined by a catheter guidewire. The catheter includes a balloon or stent mounted about the outer catheter (20). There is no third catheter which would appear capable of providing a retaining sleeve for a self-expanding stent. The Examiner merely "maintains the position that this modification would have been obvious" without providing a motivation or even providing all elements of the claims which would be necessary to accomplish the modification.

The Advisory Action does not respond to other arguments and deficiencies of the reference presented and noted earlier.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Date: March 15, 2010

Respectfully submitted,

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